UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

NADINE A. WHITE, Individually and as Personal Representative of the Estate of MORIAH A. MCCULLOUGH, Deceased, and DAVID B. MCCULLOUGH, Individually,
Plaintiffs,

-v-

SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE, a Pennsylvania Corporation,
Defendant.

Case No. 1:07-cv-529

HONORABLE PAUL L. MALONEY

OPINION AND ORDER GRANTING DEFENDANT'S MOTION FOR JUDGMENT ON THE PLEADINGS AND DENYING PLAINTIFFS' REQUEST TO AMEND THE COMPLAINT

This Court has before it Defendant SmithKline Beechham Corporation's Motion for Judgment on the Pleadings (Dkt. No. 71). Plaintiffs filed a response to the motion (Dkt. No. 97) and requested oral argument. As part of the response, Plaintiffs request leave to file an amended complaint in the event this Court decides to grant Defendant's motion. Defendant filed a reply to the response (Dkt. No. 99). Having read the briefs, this Court finds the parties have adequately addressed the law and facts and concludes oral argument is unnecessary. *See* W.D. MICH. L.CIV.R. 7.2(d).

I. STANDARD OF REVIEW

A motion for judgment on the pleadings under 12(c) of the Federal Rules of Civil Procedure applies the same standards as a motion to dismiss under Rule 12(b)(6). *Lindsay v. Yates*, 498 F.3d 434, 438 (6th Cir. 2007). Under the applicable standard, the court reviews the complaint in a light

most favorable to the non-moving party, accepting as true all well-pled factual allegations. *Commercial Money Ctr., Inc. v. Illinois Union Ins. Co.*, 508 F.3d 327, 336 (6th Cir. 2007) (citing *United States v. Moriarty*, 8 F.3d 329, 332 (6th Cir. 1993)). The court need not accept as true legal conclusions or unwarranted factual inferences contained in the pleadings. *Id.* (citing *Gregory v. Shelby County*, 220 F.3d 433, 446 (6th Cir. 2000)). To survive the motion, "the complaint must contain direct or inferential allegations respecting all the material elements under some viable legal theory." *Id.* (citing *Mezibov v. Allen*, 411 F.3d 712, 716 (6th Cir. 2005)). *See also Shuptrine v. McDougall Littell*, No. 1:07-cv-181, 2008 WL 400453 at * 1 (E.D. Tenn. Feb. 12, 2008) (ruling on a Rule 12(c) motion and identifying the standard for a motion to dismiss under Rule 12(b)(6), in light of *Bell Atl. Corp. v. Twombly*, ___ U.S. ___, 127 S.Ct 1955, 1974 (2007), as whether the complaint pleads enough facts to state a claim to relief that is plausible on its face).

II. WELL-PLED FACTUAL ALLEGATIONS IN PLAINTIFFS' COMPLAINT

The complaint generally makes the following allegations. Defendant SmithKline Beecham Corporation d/b/a GlaxoSmithKline (GSK) manufactures the prescription medication paroxetine, a selective serotonin reuptake inhibitor (SSRI) sold under the trade name Paxil®. (Complaint ¶ 8). In December 1992, the United States Food and Drug Administration (FDA) approved Paxil for treating depression in adult patients. (*Id.*). Paxil has not ever been approved by the FDA for use by children or adolescents. (*Id.*).

GSK has tested Paxil on children and adolescents. (Complaint ¶¶ 9, 11, and 13). GSK's studies have shown Paxil is ineffective for treatment of depression in children and adolescents, and is associated with an increased risk of suicidality in that population. (*Id.* ¶¶ 10, 11 and 13). In spite of the studies, GSK informed its sales representatives that Paxil was safe for the treatment of

adolescent depression, but did not inform the sales representatives about the associated risk of suicidality. (*Id.* ¶ 21). In 2003, the FDA reviewed the data from GSK's pediatric clinical trials and recommended that Paxil not be used for the treatment of children and adolescents with depression. (*Id.* at 25). In 2004, the FDA found there was a class-wide connection between SSRI use in pediatric patients and suicide-related events. (*Id.* ¶ 32). The FDA then requested GSK add a black-box warning to the Paxil label regarding the risk. (*Id.*). In 2005, GSK added the warning to the Paxil label. (*Id.* ¶ 33).

The complaint alleges Moriah McCullough, plaintiffs' decedent, a Michigan resident, died on May 31, 2001. At the time, Ms. McCullough was sixteen years old (Complaint ¶ 6) and was taking Paxil (*Id.* ¶ 1). Ms. McCullough died when she hanged herself. (*Id.* ¶ 6). She had been taking Paxil for three months. (*Id.* ¶ 37).

The complaint alleges seven counts against Defendant GSK. Count I alleges negligence related to the research, manufacture, sale, merchandising, advertisement, promotion, labeling, analysis, distribution, and marketing of Paxil. (Complaint ¶ 38). Count II alleges "negligent pharmaco-vigilance" arising from the on-going duty to continually monitor, test and analyze data regarding the safety, efficacy and prescribing practices of Paxil. (*Id.* ¶ 43). Count III alleges strict liability related to deficiencies in the information about Paxil given to physicians, Plaintiffs and Ms. McCullough. (*Id.* ¶53). Count IV alleges breaches of express warranty arising from the various sources information from GSK which warranted to physicians, Plaintiffs and Ms. McCullough, that Paxil was safe for use by pediatric patients. (*Id.* ¶ 59). Count V alleges fraud related to the various efforts by GSK to mislead the medical profession and the public about the dangers of Paxil's side effects. (*Id.* ¶ 68). Count VI alleges loss of consortium and loss of income. (Complaint ¶ 78).

Finally, Count VII alleges a cause of action for survival. (*Id.* ¶ 80).

III. DISCUSSION

The central issue is whether Plaintiffs may maintain the action on the basis that the United States Food and Drug Administration never approved the use of Paxil, a prescription medication, by children and adolescents. An alternative way of approaching the issue would be to ask whether Plaintiffs may maintain the action in light of the United States Food and Drug Administration's approval of the use of Paxil by adults. Phrased this way, Defendant's motion tests the viability of the allegations of various common law torts in the complaint subject to the immunity provided by statute.[1]

A. MICHIGAN LAW[2]

In 1978, Michigan enacted a statute which established certain evidentiary standards for product liability actions. MCL § 600.2946; *Duronio v. Merck & Co., Inc.*, No. 267003, 2006 WL1628516 at * 2 (Mich. App. June 13, 2006) (per curiam). *See Taylor v. Gate Pharm.*, 658 N.W.2d 127, 130 (Mich. 2003). In 1995, Michigan amended its product liability statute to provide

[1]Motions to dismiss may be premised on certain affirmative defenses. *Rausch v. Day & Night Mfg. Corp.*, 547 F.2d 697, 702 (6th Cir. 1978) ("the prevailing rule is that a complaint showing on its face that relief is barred by an affirmative defense is properly subject to a 12(b)(6) motion to dismiss" (citing 5 Wright & Miller, *Federal Practice and Procedure: Civil* § 1357 (1969) at 607)). *See e.g., New England Health Care Employees Pension Fund v. Ernst & Young, LLP*, 336 F.3d 495, 501 (6th Cir. 2003) (statute of limitations); *GTE North, Inc. v. Strand*, 209 F.3d 909, 915 (6th Cir. 2000) (subject matter jurisdiction); *Collyer v. Darling*, 98 F.3d 211, 222 (6th Cir. 1996) (absolute and qualified immunity).

[2]The suit was originally filed in the eastern district of Pennsylvania. The suit was transferred to this district through an order granting Defendant's motion to transfer venue. The Pennsylvania district court held that Michigan law applied under the appropriate choice of law analysis. Defendant asserts that decision is binding under the law of the case doctrine. (Brief in Support at 3). Plaintiff has not challenged that assertion.

a broad defense, subject to two exceptions, to drug manufacturers in a product liability action where the drugs comply with FDA standards and labeling. MCL § 600.2946(5); *Taylor*, 658 N.W. 2d at 131. *See also Griffus v. Novartis Pharm. Corp.*, No. 06-10891, 2006 WL 2583129 at * 1 (E.D. Mich. Sept. 6, 2006); *Zammit v. Shire US, Inc*., 415 F. Supp.2d 760, 765 (E.D. Mich. 2006); *Garcia v. Wyeth-Ayerst Labs.*, 265 F. Supp.2d 825, 828 (E.D. Mich. 2003) (*Garcia I*).

The statute states

> In a product liability action against a manufacturer or seller, a product that is a drug is not defective or unreasonably dangerous, and the manufacturer or seller is not liable, if the drug was approved for safety and efficacy by the United States food and drug administration, and the drug and its labeling were in compliance with the United States food and drug administration's approval at the time the drug left the control of the manufacturer or seller. However, this subsection does not apply to a drug that is sold in the United States after the effective date of an order of the United States food and drug administration to remove the drug from the market or to withdraw its approval. This subsection does not apply if the defendant at any time before the event that allegedly caused the injury does any of the following:
>
> (a) Intentionally withholds or misrepresents to the United States food and drug administration information concerning the drug that is required to be submitted under the federal food, drug and cosmetic act, chapter 675, . . . and the drug would not have been approved, or the United States food and drug administration would have withdrawn approval for the drug if the information were accurately submitted.
>
> (b) Makes an illegal payment to an official or employee of the United States food and drug administration for the purpose of securing or maintaining approval of the drug.

MCL 600.2946(5) (citations omitted).

The Michigan Legislature defined various terms and phrases within the product liability statute.

> "Product liability action" means an action based on a legal or equitable theory of liability brought for the death of a person or for injury to a person or damage to property caused by or resulting from the production of a product.

MCL § 600.2945(h).

> "Production" means manufacture, construction, design, formulation, development of standards, preparation, processing, assembly, inspection, testing, listing, certifying, warning, instructing, marketing, selling, advertising, packaging, or

labeling.

MCL § 600.2945(i).

Thus, under Michigan's statutory scheme, a suit against a drug manufacturer for injury or death related to the drug is a product liability suit when the plaintiff alleges fault in the standards, testing, warning, instruction, marketing, selling, advertising or labeling of the drug. A drug manufacturer enjoys "an absolute defense" from such product liability suits if (1) the FDA approved the safety and efficacy of the drug and (2) the drug and the labeling were in compliance with the FDA's approval at the time the drug left control of the manufacturer, unless either the fraud or bribery exception applies. *Taylor*, 658 N.W.2d at 131.

Six years after the Michigan Legislature amended the product liability statute, the United States Supreme Court generally invalidated state common law tort claims for fraud-on-the-FDA. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 348 (2001); *Garcia I* at 831. *See also Kemp v. Medtronic, Inc.*, 231 F.3d 216, 236 (6th Cir. 2000) (holding, prior to *Buckman*, that common law suits premised on fraud-on-the-FDA could not be reconciled with the Sixth Circuit's earlier holding that there is no implied right of action for a violation of the Federal Food, Drug and Cosmetics Act). The Supreme Court held that state-law fraud-on-the-FDA claims were preempted by federal law (the Federal Food, Drug and Cosmetic Act). *Buckman*, 531 U.S. at 348. The Court explained the federal statute empowers the FDA to punish fraud (*Id.*) and that the FDA has authority, through federal regulations, to investigate suspected fraud (*Id.* at 349).

Garcia I involved allegations that a prescription drug caused liver damage to the plaintiff. 265 F. Supp.2d at 828. The district court granted the defendant drug manufacturer's motion for summary judgment because the plaintiff failed to offer any evidence supporting either the bribery

or misrepresentation allegations in the complaint. *Id.* at 830. Because there was no factual dispute that the drug was approved by the FDA before it was prescribed to the plaintiff, the statute provided immunity to the manufacturer. *Id.* The court also denied the plaintiff's motion for partial summary judgment in which she alleged the product liability statute violated the federal constitution. *Id.* at 830-835.

Discussing the impact of *Buckman* on the state statute, Judge Lawson concluded the plaintiff was in a "Catch-22" which did not render the statute unconstitutional. *Id.* at 832. He explained that when the FDA has not acted upon allegations of fraud or bribery,

> *Buckman* teaches that state tort remedies requiring proof of fraud committed against the FDA are foreclosed since federal law preempts such claims. Section 600.2946(5), therefore, sends plaintiffs down a dead-end road, inasmuch as it creates immunity for drug manufacturers that can be upset only by a statutory exception that federal law preempts . . .

Id. Judge Lawson reasoned (1) the state legislature could provide remedies that were illusory as the exceptions in the statute run into the Supremacy Clause and (2) the invalidity of the exceptions did not make the grant of immunity invalid because of the severability provision under MCL § 8.5. *Id.* *See Garcia v. Wyeth-Ayerst Labs.*, 385 F.3d 961, 965 (6th Cir. 2004) (*Garcia II*) (characterizing Judge Lawson's opinion as having concluded the exceptions were unconstitutional). Plaintiff appealed the denial of her motion for partial summary judgment, but not the decision to grant the defendant's motion for summary judgment. *Garcia II* at 964 n. 1.

This Court is obligated to follow Sixth Circuit precedent. *Garcia II* is the only case in which the Sixth Circuit has issued an opinion, published or unpublished, where MCL § 600.2946(5) is at issue. The Sixth Circuit noted the *Buckman* case involved a medical device rather than a prescription drug and found the same reasoning and conclusion applied to suits against drug

manufacturers. *Garcia II* at 965-966 (agreeing with the district court that "state tort remedies requiring proof of fraud committed against the FDA are foreclosed since federal law preempts such claims" (quoting *Garcia I* at 832)).

The Sixth Circuit affirmed the district court's decision. The court concluded the statutory exemptions in MCL § 600.2946(5) were unconstitutional, as applied. *Garcia II* at 966. The court explained that, in a different case where a plaintiff presents evidence of federal findings of bribery or fraud on the FDA, the exceptions are not unconstitutional, but where a plaintiff, like Ms. Garcia, merely alleges bribery or fraud on the FDA but offers no federal findings, the exceptions are unconstitutional. *Id.* The court then applied Michigan's general statutory severability provision, MCL § 8.5, to the product liability statute. *Id.* at 967. The court concluded unconstitutional exceptions could be severed from the general grant of immunity, leaving the general grant of immunity enforceable. *Id.*

As a result of the Michigan statute and Sixth Circuit application of the preemption doctrine, most suits of the instant nature in Michigan against drug manufacturers are functionally foreclosed. In order to maintain a product liability suit against a drug manufacturer under Michigan law, a plaintiff need allege more than the elements of the common law tort. A plaintiff must also allege the federal government has established that the drug manufacturer either committed fraud against the FDA or bribed an FDA official. *See Garcia II* at 696-697; *Ammend v. BioPort, Inc.*, No. 1:05-cv-182, 2006 WL 1050509 at * 3 (W.D. Mich. April 19, 2006) (Quist, J.) ("a plaintiff may not establish the exceptions through proof of fraud or bribery, but must instead show the FDA has made its own determinations of fraud or bribery"); *Garcia I* at 831 ("section 600.2946(5) effectively mandates a plaintiff to offer evidence of fraud on the FDA as an element of its product liability claim

against a drug manufacturer."). *But see Desiano v. Warner-Lambert Co.*, 467 F.3d 85, 96 (2d Cir. 2007) ("the Michigan Supreme Court has indicated that proof of fraud against the FDA is not even an element of a products liability claim like the one here brought. . . . We take this to mean that the Michigan law in question does no more than to create a defense that drug makers may invoke, if they so decide, and that it is not up to the plaintiff to prove fraud as an element of his or her claim.") *cert. denied*, ___ U.S. ___, 2008 WL 552875 (March 3, 2008).

B. DEFENDANT'S MOTION

Defendant GSK argues Michigan law prohibits Plaintiffs' product liability suit. Plaintiffs admit Paxil has been approved for use in adults. (Complaint ¶ 8). Plaintiffs do not allege that GSK has not complied with the FDA's labeling requirements. The complaint supports the inference that labeling for Paxil has complied with the requirements imposed by the FDA. (*See* Complaint ¶¶32 and 33). The complaint generally alleges a nefarious campaign by Defendant to influence the medical community into prescribing Paxil "off-label"[3] to patient populations other than those for which the drug was approved, in spite of known risks to that population. Plaintiffs do not put forth any evidence that the FDA has found either fraud or bribery such that Plaintiffs' action might fall

[3]"Off-label" refers to the use of drugs and medical devices for purposes other than that which the FDA has approved. *Buckman*, 531 U.S. at 350; *Planned Parenthood Cincinnati Region v. Taft*, 444 F.3d 502, 505 (6th Cir. 2006) ("absent state regulation, once a drug has been approved by the FDA, doctors may prescribe it for indications and in dosages other than those expressly approved by the FDA. This is a widely employed practice known as "off-label" use. Off-label use does not violate the federal law or FDA regulations because the FDA regulates the marketing and distribution of drugs in the United States, not the practice of medicine, which is the exclusive realm of individual states."); *Blain v. SmithKline Beecham Corp.*, 240 F.R.D. 179, 182 n. 6 (E.D. Pa. 2007) ("the term "off-label" refers to the use, prescription or marketing of an FDA-approved drug for an unapproved use, such as, in an unapproved population, or for a condition other than for what it has been approved" (citing Steven R. Salbu, *Off-Label Use, Prescription and Marketing of FDA-Approved Drugs: An Assessment of Legislative and Regulatory Policy*, 51 Fla. L.Rev. 181, 188-189 (1999))).

into one of the two exceptions under the Michigan statute.

Plaintiffs' response to the motion characterizes the complaint as a "failure to warn" case. (Brief in Opposition at 1). Plaintiffs argue the Michigan statute does not apply because the FDA never approved the use of Paxil by children and adolescents. (*Id.* at 2 and 13). Plaintiffs assert they have "documents and testimony supporting application of exception (a)" of the Michigan statute, but they have refrained from citing or attaching evidence outside the pleadings because this is a motion for judgment on the pleadings. (*Id.* at 12).

Assuming the well-pled facts in the complaint as true, as this Court must for this motion, under the plain language of the statute, Defendant GSK is protected from this product liability suit. The Michigan Legislature provided immunity for drug manufacturers for products approved by the FDA, so long as the product and its labeling meet the FDA standards. Through the definition of "production," the statute extends the protection from suits broadly to a myriad of activities a manufacturer might perform related to the product. The statute does not limit the protection to situations when the drug is used for its approved purposes. Should the Legislature wish to limit the protection available to "off-label" uses of the drug, it may do so. Until such an amendment is enacted, this Court must interpret the statute as it is written. Under Michigan law, the actions of Defendant GSK alleged in the complaint are protected from a lawsuit because Defendant has complied with FDA regulations.

This outcome is consistent with prior state and federal decisions interpreting the same statute. The *Griffus* opinion from the Eastern District of Michigan address a similar fact pattern. 2006 WL 2583129. The plaintiff in *Griffus* participated in a clinical trial of the drug Trileptal, a drug with FDA approval for treatment of seizures and epilepsy. In response to the defendant's motion to

dismiss based on Michigan's product liability statute, the plaintiff argued the drug was provided to her for the purpose of treating a condition for which the drug had not been approved. Judge Edmunds rejected the plaintiff's argument, reasoning that the Michigan Legislature "was certainly aware" that drugs could be used for purposes other than those approved by the FDA and nevertheless opted to provide blanket immunity. *Griffus*, 2006 WL 2583129 at *2.

The plaintiff in *Griffus* also characterized her suit as a failure to warn case, arguing that the statute protected drug companies for negligence in manufacturing. Again, Judge Edmunds disagreed, pointing out the statutory defense from product liability suits extends well beyond negligence in manufacturing. *Id.* Similarly, in *Duronio*, the plaintiff alleged defendant Merck disseminated information to the public which downplayed or concealed potential cardiovascular risks, among other things. 2006 WL 1628516. Plaintiff sought a refund of the purchase price of the drugs as well as costs and expenses related to medical consultations recommended by the FDA when the drug (Vioxx) was withdrawn from the market. The state trial court granted the defendant's motion for summary judgment on the basis that the complaint was really a product liability claim. The Michigan Court of Appeals affirmed that decision. The court reasoned that defendant's marketing, selling, advertising, packaging, or labeling all fell within the statutory definition of "production." *Duronio*, 2006 WL 1628516 at * 5.

C. PLAINTIFFS' REQUEST FOR LEAVE TO AMEND THE COMPLAINT

In the event this Court elects to grant the motion, Plaintiffs have requested leave to amend the complaint. Plaintiffs insist they have a good faith belief that a viable cause of action can be pled consistent with MCL § 600.2946(5). (Brief in Response at 14).

The decision to grant a plaintiff's motion to amend the pleadings is within the district court's

discretion. *Brumbalough v Camelot Care Ctrs., Inc*., 427 F.3d 996, 1001 (2005). After a responsive pleading is filed, a plaintiff may only amend the pleadings by leave of court or by written consent of the adverse party and leave shall be freely given when justice so requires. FED. R. CIV. P. 15(a). When deciding whether to grant a motion to amend, a court should consider whether there has been undue delay in filing the amendment, lack of notice to the opposing parties, bad faith by the moving party, repeated failure to cure deficiencies by previous amendments, undue prejudice to the opposing parties, and futility of amendment. *Brumbalough*, 427 F.3d at 1001. Generally, an amendment would be futile if the amended complaint could not withstand a 12(b)(6) motion. *Rose v. Hartford Underwriters Ins. Co.*, 302 F.3d 417, 420 (6th Cir. 2000) (citing *Thiokol Corp. v. Dep't of Treasury, State of Michigan, Revenue Div.*, 987 F.2d 376, 382-383 (6th Cir. 1993).

Motions for leave to file an amended complaint under Rule 15(a) are governed by FED. R. CIV. P. 7(b). *Evans v. Pearson Enters., Inc.*, 434 F.3d 839, 853 (6th Cir. 2006). Rule 7(b) requires a motion to state the grounds upon which it is made with particularity. *Id. See Begala v. PNC Bank, Ohio, Nat'l Ass'n*, 214 F.3d 776, (6th Cir. 2000). Local Rule 5.7(f) requires the proposed pleading as an attachment to be filed as an attachment to a motion for leave to file an amended complaint. W.D. MICH. L.CIV.R. 5.7(f).

Plaintiffs' motion is denied for lack of particularity and for futility. Plaintiffs have not identified with any particularity how they would amend the complaint. A belief, even one in good faith, that an amended complaint could be drafted to survive the Michigan statute does not provide the sort of particularity required by Rule 7(b). Neither does a good faith belief suffice as an attachment to the motion to amend as required by the local rules. In light of the above discussion of MCL § 600.2946(5), the motion is also denied for futility. Plaintiffs concede Paxil has been

approved by the FDA and have not made any allegations that the drug has been labeled in a manner not in compliance with FDA approval. Neither have Plaintiffs alleged the FDA has found either fraud or bribery such that one of the exceptions in the statute would apply. Under that set of facts, Defendant GSK enjoys broad immunity from product liability suits based on activities related to Paxil.

III. CONCLUSION

Plaintiffs' suit alleges causes of action against Defendant GSK that fall under the broad protections afforded to drug manufacturers under Michigan's product liability statute, MCL § 600.2946(5). Plaintiffs have not alleged any fact which would invoke either of the two exceptions contained within the statute. Accordingly, Defendant GSK's motion for judgment on the pleadings is granted.

Plaintiffs' request for leave to file an amended complaint is denied. Plaintiffs have not explained with any particularity what the amended complaint would allege. Given the broad protection afforded to drug manufacturers under the statute, any amendment would be futile.

ORDER

Defendant GSK's Motion for Judgment on the Pleadings (Dkt. No. 71) is **GRANTED.** Plaintiffs' request for leave to file an amended complaint (Dkt. No. 97) is **DENIED.**

THIS CASE IS TERMINATED. IT IS SO ORDERED.

Date: March 6, 2008

/s/ Paul L. Maloney
Paul L. Maloney
United States District Judge